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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

SISSON, BRADLEY L

ART UNIT PAPER NUMBER

1634

DATE MAILED: 08/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/980,884

Applicant(s)

BAKER, MATTHEW JOHN

Examiner

Bradley L. Sisson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 and 24-39 is/are rejected.
- 7) ☒ Claim(s) 23 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claim 1 is objected to because of the following informalities: Claims 1 contains a step “(b)” but does not contain a step “(a)”. Appropriate correction is required.

Claims

2. A series of singular dependent claims is permissible in which a dependent claim refers to a preceding claim which, in turn, refers to another preceding claim.
3. A claim, which depends from a dependent claim, should not be separated by any claim, which does not also depend from said dependent claim. In the present case, claim 32 is separated from independent claim 1 by independent claims 25, 26, and 31. It should be kept in mind that a dependent claim may refer to any preceding independent claim. In general, applicant's sequence will not be changed. See MPEP § 608.01(n).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-22 and 24-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/26872 (Blevins) in view of US Patent 5,453,382 (Novotny et al.), Stratagene and GIBCO BRL Products (GIBCO).

8. Blevins discloses a method and related device of the extraction of biochemicals from a sample containing same. As disclosed therein, a pipette is connected to a pipette tip wherein the pipette tip comprises means for binding the biochemical thereto.

9. Blevins, page 4, second full paragraph, teaches explicitly of passing the sample fluid back and forth over the "compartment in the pipette," adding "[n]aturally, this bidirectional fluid sequence through the pipette and extraction medium may be iterated any number of times with

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various fluids to enable a greater number of procedures to be conducted.” At page 8, bridging to page 9, Blevins exemplifies the passage of a sample fluid through a solid phase extraction means and then passing the fluid back through said SPE whereby the pipette is used to effect reversible suction means.

10. Blevins also discloses on page 4 that the device and related method may be practiced where multiple compartments and pipettes.

11. Blevins, page 7, teaches that the extraction method and related device can be designed to bind “desired analytes from a given sample” by altering the solid phase used in the compartment.

12. While Blevins speaks to broad applicability of the extraction method and device, isolation of nucleic acids is not specifically identified. Also, while Blevins does teach of using a pipette, he does not teach of using a syringe.

13. Novotny et al., Figure 1, depicts a syringe connected to a container wherein analytes of interest can bind.

14. Novotny et al., column 6, list a plethora of suitable biological samples.

15. Novotny et al., column 6, lines 38-40, also teach of the “packing material” (applicant’s “solid phase”) being held in place through use of a frit. Said frit is considered to meet the limitations of claims 19, 20, and 30.

16. Novotny et al., do not teach explicitly of isolating nucleic acids.

17. Stratagene, page 81, teaches explicitly of using poly(A) Quick columns to isolate RNA wherein the columns are connected to a syringe. Stratagene also disclose the columns comprising a capture moiety (oligo (dT)) on cellulose.

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18. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method and device of Blevins and Novotny et al., with that of Stratagene a such would have allowed for the adaptation of aid device and related method of use whereby one would be able to isolate the nucleic acid of interest. As presented above, the aspect of using reversible suction means, e.g., pipettes and syringes, was well known as was the formulation and arrangement of various extraction devices. As presented by both Blevins and Novotny et al., the specificity of the solid phase can be altered by simply changing the composition of said solid phase, and that Stratagene teaches just such an extraction device that is designed to be used in a method for isolating nucleic acids. In view of the explicit guidance to the commercial availability of nucleic acid extraction means, the detailed teachings of methods for isolating analytes of interest, and the profound interest that exists in nucleic acids, said ordinary artisan would have been amply motivated to have devised a method and device for he isolation of same, and would have had a most reasonable expectation of success.

19. Therefore, and in the absence of convincing evidence to he contrary, claims 1-22 and 24-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/26872 (Blevins) in view of US Patent 5,453,382 (Novotny et al.), Stratagene and GIBCO BRL Products (GIBCO).

Conclusion

20. Claim 23 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751.

The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

22. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

23. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
22 August 2005